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TO:

Name: Mail Stop APPEAL BRIEF-Patents
Group Art Unit 3773/Examiner Melanie Ruano Tyson

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Fax No.: 571-273-8300

Subject: U.S. Patent Application No. 10/098,683
Gary Karlin Michelson
Filed: March 15, 2002
SPINAL IMPLANT CONTAINING MULTIPLE BONI
GROWTH PROMOTING MATERIALS (as amend

FROM:

Name: Thomas H. Martin, Esq.

Phone No.: 330-877-2277

No. of Pages (including this): 9

Date: December 5, 2008

Confirmation Copy to Follow: NO

Attorney Docket No. 101.0042-05000
Customer No. 22882
Confirmation No.: 7210

Message:

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Attorney Docket No.: 101.0042-05000
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gary Karlin Michelson

Serial No: 10/098,683

Filed: March 15, 2002

For: SPINAL IMPLANT CONTAINING
MULTIPLE BONE GROWTH
PROMOTING MATERIALS
(as amended)

Confirmation No.: 7210

Art Unit: 3773

Examiner: Melanie Ruano Tyson

Mail Stop APPEAL BRIEF-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Transmitted herewith is a Reply Brief in reply to the Examiner's Answer of October 29, 2008 in the above-identified application.

- ☒ No additional fee is required.
- ☐ Applicant hereby requests a ***-month extension of time to respond to the above Office Action.
- ☐ The total amount of \$*** to cover the above fees is to be charged to Deposit Account No. 50-3726.
- ☒ The Commissioner is hereby authorized to charge any deficiencies of fees associated with this communication or credit any overpayment to Deposit Account No. 50-3726.
- A copy of this sheet is enclosed.**
- ☒ Any filing fees under 37 C.F.R. § 1.16 for the presentation of extra claims
- ☒ Any patent application processing fees under 37 C.F.R. § 1.17

Respectfully submitted,

MARTIN & FERRARO, LLP

Date: December 5, 2008

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Sir:

REPLY BRIEF

Appellant submits the following reply to the Examiner's Answer dated October 29, 2008 ("Answer"). Before replying to the Answer, however, Appellant notes that under the Real Party in Interest it should have indicated that the real party in interest is Warsaw Orthopedic, Inc. ("Appellant"), the assignee of record, which is a subsidiary of Medtronic, Inc.

I. Introduction

In the Answer, the Examiner responds to the Appeal Brief, but does not rebut the arguments presented by Appellant. The Answer is derived primarily from the Final Action of March 14, 2008 ("Final Action") and the Advisory Action of May 23, 2008 ("Advisory Action"). Therefore, rather than repeating arguments from the Appeal Brief countering the Examiner's arguments from the Final Action and Advisory Action, additional argumentation clarifying and supplementing Appellant's positions is provided herein. Appellant addresses the Examiner's Answer by using the section/sub-section numbering utilized in the Appeal Brief.

Reply Brief 12-5-08.doc

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Reply to Examiner's Answer of October 29, 2008

II. Argument

A. Section I of the Appeal Brief:

The present invention as claimed in claims 54-65, 67-78, and 104-106 (including independent claim 54) is patentable over the Examiner's rejection under the written description requirement under 35 U.S.C. § 112, first paragraph.

According to the BPAI, "[t]he test [under the written description requirement of 35 U.S.C. § 112, first paragraph] is whether the originally filed specification disclosure reasonably conveys to a person having ordinary skill [in the art] that applicant had possession of the subject matter later claimed." (*In re Sorenson*, Appeal No. 649-98, 1987 Pat. App. Lexis 17, *3 (BPAI 1987), citing *In re Kaslow*, 707 F.2d 1366 (Fed. Cir. 1983).) Accordingly, to satisfy the written description requirement, the understanding conveyed to one of ordinary skill in the art by the specification is considered, "rather than the presence or absence of literal support in the specification for the claim language." (*In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983).)

As discussed in the Appeal Brief, the field of spinal surgery is an art of relatively high skill and knowledge. Therefore, Appellant submits that one of ordinary skill in the art would recognize that the solid states of hydroxyapatite and hydroxyapatite tricalcium phosphate, and the liquid state of bone morphogenetic protein (BMP) are inherent properties of those materials when used to promote bone fusion.

Furthermore, "the inquiry into whether the [written] description requirement is met must be determined on a case by case basis and is a question of fact." (*In re Sorenson*, Appeal No. 649-98, 1987 Pat. App. Lexis 17, *3 and *4 (BPAI 1987), citing *In re Wilder*, 736 F.2d 1516 (Fed. Cir. 1983).) "[T]he examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in appellant's specification disclosure a description of the invention defined by the claims." (*In re Sorenson*, Appeal No. 649-98, 1987 Pat. App. Lexis 17, *4 (BPAI 1987), citing *In re Wertheim*, 541 F.2d 251 (CCPA 1976).)

Appellant submits that the Examiner has not met such a burden for rejecting claims 54-65, 67-78, and 104-106 under the written description requirement of 35

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Reply to Examiner's Answer of October 29, 2008

U.S.C. § 112, first paragraph. The Examiner indicates that "the terms 'liquid' and 'solid' cover other materials in addition to those disclosed by the appellant," and "although the materials disclosed by the appellant may inherently contain these properties, the appellant did not disclose all liquid and solid fusion promoting materials." (Answer, paragraph bridging pages 4 and 5.) However, it was unnecessary to disclose all liquid and solid fusion promoting materials in the specification to support the claimed invention.

As discussed above, one of ordinary skill in the art would recognize the inherent properties of hydroxyapatite, hydroxyapatite tricalcium, and BMP when used to promote bone fusion. Therefore, the specification as originally filed would reasonably convey to one of ordinary skill in the art that the liquid and solid fusion promoting materials were disclosed therein. Hence, one of ordinary skill in the art would conclude that Appellant was in possession of the invention as claimed. Therefore, no new matter has been introduced into the claims. Accordingly, Appellant submits that the Examiner's rejection of claims 54-65, 67-78, and 104-106 under 35 U.S.C. § 112, first paragraph, cannot be maintained.

B. Section II of the Appeal Brief:

The Abstract is adequately supported by the original disclosure, and hence, overcomes the Examiner's objection under 35 U.S.C. § 132(a).

Given that claims 54-65, 67-78, and 104-106 are patentable over the Examiner's rejection under 35 U.S.C. § 112, first paragraph, Appellant submits that the Abstract is adequately supported by the original disclosure. Hence, no new matter has been introduced in the Abstract, and the Examiner's objection to the June 18, 2007 Amendment under 35 U.S.C. § 132 has been overcome.

C. Section III of the Appeal Brief:

The present invention as claimed in claims 54-65, 67-90, and 92-108 (including independent claims 54 and 79) is patentable over the Examiner's rejection under 35 U.S.C. § 103(a) based on U.S. Patent No. 5,026,373 to Ray ("Ray").

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As discussed in the Appeal Brief, Ray is limited to disclosing fusion cages (10) and (50) that can be packed with the bone chips or cancellous bone. (See Ray, Abstract and column 10, lines 9-12.) However, independent claim 54 recites an interbody spinal fusion implant combined with liquid and solid fusion promoting materials, and independent claim 79 recites an interbody spinal fusion implant combined with bioactive and bioresorbable materials. Although the bone chips or cancellous bone of Ray are solid and bioresorbable materials, the bone chips or cancellous bone are not liquid or bioactive materials. Accordingly, Ray does not teach or suggest each and every element of Appellant's invention as recited in Independent claims 54 and 79.

Furthermore, besides making the assertion that "it would have been obvious to one having ordinary skill in the art at the time the application was filed to employ the bone growth promoting materials as claimed in Ray's implant to promote new bone growth (emphasis added)," the Examiner has not pointed to any teaching or suggestion in the prior art affording such an assertion. (Answer, paragraph bridging pages 3 and 4.) Furthermore, Appellant submits that the Examiner overestimates the level of ordinary skill in the art at the time the application was filed to support the modification of Ray.

The references, U.S. Patent Nos. 5,344,654 ("Rueger") and 5,344,457 ("Pillar"), cited by the Examiner for showing the level of ordinary skill in the art do not disclose providing a liquid fusion promoting material and a solid fusion promoting material in the hollow interior of an implant or providing a bioactive material and a bioresorbable material in the hollow interior of an implant. Instead, the exteriors of the implants of Rueger and Pillar include bone growth promoting materials. Therefore, while Appellant submits that one of ordinary skill in the art of spinal surgery would recognize, as discussed above, the solid states of hydroxyapatite and hydroxyapatite tricalcium phosphate, and the liquid state of BMP, it would not have been obvious to one of ordinary skill in the art to modify Ray to use the liquid and solid fusion promoting materials (of Independent claim 54) and the bioactive and bioresorbable materials (of Independent claim 79) at the time the application was filed.

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Moreover, if either Rueger or Pillar were used as part of a rejection with Ray under 35 U.S.C. § 103(a), Appellant submits that Rueger and Pillar are non-analogous art to the Appellant's invention recited in independent claims 54 and 79. According to MPEP § 2141.01, "a reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole." Hence, the pertinence of a reference is determined by if the reference can be logically associated with the claimed invention.

Rueger and Pillar are not related to spinal fusion or spinal fusion implants as recited in independent claims 54 and 79, and hence, Appellant submits that Rueger and Pillar are in a different field of endeavor as the claimed invention. Furthermore, only the exteriors of the implants of Rueger and Pillar include bone growth promoting materials. As such, Rueger and Pillar are concerned with securing the implants thereof to bone, not providing liquid and solid fusion promoting materials (claim 54) or providing bioactive and bioresorbable materials (claim 79) in the hollow interiors of the implants recited therein to facilitate fusion between bones. Besides being associated with a different field of endeavor, Rueger and Pillar are directed to solving a different problem than the Appellant's claimed invention. Hence, Appellant submits that Rueger and Pillar do not logically commend themselves for consideration in light of the claimed invention, and the pertinence thereof is significantly limited. Accordingly, Rueger and Pillar are non-analogous art to the claimed invention of independent claims 54 and 79, and could not be used with Ray in facilitating a rejection thereof.

For the above-discussed reasons, and those included in the Appeal Brief, Appellant submits that independent claims 54 and 79 are not obvious in view of the Examiner's rejection under 35 U.S.C. § 103(a) based on Ray.

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III. Conclusion

Appellant submits that independent claims 54 and 79 are patentable and that dependent claims 55-65, 67-78, 80-90, and 92-108, dependent from one of independent claims 54 and 79, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim. Therefore, Appellant respectfully requests the Board to reverse the Examiner's rejections and objection, and allow claims 54-65, 67-90, and 92-108.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. § 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,
MARTIN & FERRARO, LLP

Dated: December 5, 2008

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